

REMARKS:

The following remarks are submitted as a full and complete response to the Office Action issued on December 18, 2008. Applicants respectfully request consideration of the following remarks since they provide a sufficient submission to place the present application in condition for allowance.

Rejection of Claims 1-49 and 66 under 35 U.S.C. §103(a)

Rule 131 Declaration

The Patent Office has maintained the obviousness rejections, alleging that the 131 declaration submitted June 19, 2008 ("131 Declaration") is insufficient to establish diligence from a date prior to the date of reduction to practice of the Shamar reference to either a constructive reduction to practice – the filing date of the present application -- or an actual reduction to practice. Applicants respectfully disagree.

37 CFR 1.131(b) provides three ways in which an applicant can establish prior invention of the claimed subject matter: (A) showing (actual) reduction to practice of the invention prior to the effective date of the reference; or (B) showing conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or (C) showing conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice.) See MPEP 715.07, III.

Thus, diligence is required only when the claimed invention was conceived earlier than the effective date of the prior art reference, but was reduced to practice

actually or constructively after the effective date of the prior art reference. However, as established in the 131 Declaration, the claimed invention was actually reduced to practice prior to August 25, 2003 -- the effective date of the Shamar reference -- and thus proof of diligence is not required to antedate the Shamar reference.

"In general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose." *Id.* As explained below, the 131 Declaration as previously filed is sufficient to establish an actual reduction to practice of the claimed invention.

Both Exhibit 1 and Exhibit 2 clearly show an actual production of Batch No:R1K1068 of Formula No.:3322-S05-5. Exhibit 1 shows the details of the composition of the formulation containing a first component for controlled release and a second component for immediate release. Exhibit 1 also shows that each component listed therein was actually weighed and checked for production of Batch No.R1K1068. See pages 3, 4 and 6-8, the column entitled "wgh'd By" and "Ck'd By." The actual production of Batch No.R1K1068 using the composition described in Exhibit 1 is clearly shown in Exhibit 2. Exhibit 2 is the Manufacturing Directions, which contains instructions on (1) producing tablets containing nitrofurantoin monohydrate formulation; (2) producing tablets containing nitrofurantoin macrocrystals; and (3) encapsulation of the two types of tablets for producing nitrofurantoin monohydrate/macrocrystals capsules. Each step of these instructions requires signatures and dates by personnel who actually performed the step and who checked the performance of the step. Exhibit 2 clearly shows that these entries of signatures and dates were made in each step. As stated in section 3 of the 131 Declaration, "[a]fter these Master Formula pages and the

Manufacturing Directions pages were prepared and approved, the handwritten entries that appear on these documents were made, signed and dated contemporaneously with the work described therein.” The 131 Declaration clearly states that “[t]he originals of these two documents including the handwritten entries were prepared and/or approved prior to August 25, 2003.” Therefore, Exhibit 2 fully establishes that each step described in the Manufacturing Directions was actually performed and approved. The 131 Declaration explains in detail that the formulation of nitrofurantoin monohydrate/macrocrystals falls within the scope of the claims of the present application. Accordingly, Exhibit 2 sufficiently establishes that the formulation of nitrofurantoin monohydrate/macrocrystals as claimed in the present application was actually reduced to practice prior to August 25, 2003.

Since the 131 Declaration, together with Exhibits 1 and 2, fully establishes the actual reduction to practice of the claimed invention prior to the effective date of the Shamar reference, showing of diligence is not required to antedate the Shamar reference. Therefore, the Shamar reference does not qualify as prior art against the claimed invention. Applicants respectfully submit that since the current obviousness rejections are based on the Shamar reference as primary prior art, removal of the Shamar reference warrants withdrawal of the obviousness rejections and Applicants need not address other arguments by the Patent Office. Accordingly, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

In light of the foregoing, Applicants submit that the outstanding rejection has been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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